# HYUNDAE MEDITECH BIO HAIR SOLU TION ERUA DO- allantoin solution INNOGENE CO.,LTD

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### ACTIVE INGREDIENT

Active Ingredient: Allantoin 0.95%

#### INACTIVE INGREDIENT

Inactive Ingredients: Water, Glycerin, Butylene Glycol, Methylparaben, Phenoxyethanol, Sorbitol, Glycogen, Copper Tripeptide-1, Mannitol, Pterocarpus Marsupium Bark Extract, Serenoa Serrulata Fruit Extract, Ammonium Glycyrrhizate, Disodium Succinate, Eriobotrya Japonica Leaf Extract, Glutamic Acid, Caffeine, Zinc Gluconate, Aesculus Hippocastanum (Horse Chestnut) Seed Extract

#### **PURPOSE**

Purpose: Scalp Protectant

#### **WARNINGS**

Warnings: 1. If the following symptoms occur after product use, stop using the product immediately and consult a dermatologist (continuous use can exacerbate the symptoms): a) Red spots, swelling, itchiness, and other skin irritation b) If the symptoms above occur after the application area is exposed to direct sunlight. 2. Do not use on open wounds, eczema, and other skin irritations. 3. Storing and handling a) Close the lid after every use. b) Keep out of reach of infants and children. c) Do not store at extreme temperatures or in an area exposed to direct sunlight. 4. Wash away immediately when permeating into the eyes.

#### KEEP OUT OF REACH OF CHILDREN

Keep out of reach of infants and children.

#### **INDICATIONS & USAGE**

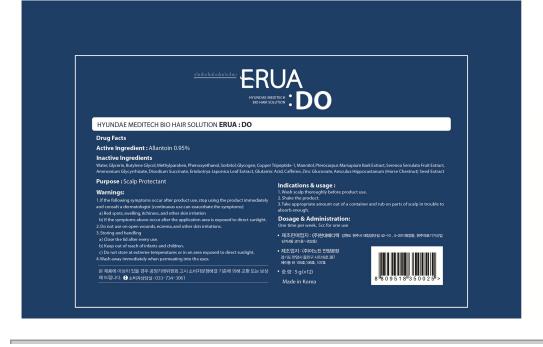
Indications & usage: 1. Wash scalp tholoughly before product use. 2. Shake the product. 3. Take appropriate amount out of a container and rub on parts of scalp in trouble to absorb enough.

#### **DOSAGE & ADMINISTRATION**

Dosage & Administration: One time per week, 5cc for one use

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





#### HYUNDAE MEDITECH BIO HAIR SOLU TION ERUA DO

allantoin solution

| Droduct | Information       |
|---------|-------------------|
| PIONICI | 111101 1111411011 |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70540-030

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

|   | Ingredient Name  | Basis of Strength | Strength      |
|---|--|-------------------|---------------|
| ı | Allantoin (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | Allantoin         | 0.04 g in 5 g |

### **Inactive Ingredients**

| mactive ingredients         |          |
|-----------------------------|----------|
| Ingredient Name             | Strength |
| Water (UNII: 059QF0KO0R)    |          |
| Glycerin (UNII: PDC6A3C0OX) |          |

## **Packaging**

| # Item Code   | Package Description | Marketing Start Date | Marketing End Date |
|---|---------------------|----------------------|--------------------|
| 1 NDC:70540-030-02  | 12 in 1 CARTON      | 08/20/2016           |                    |
| 1 NDC:70540-030-01 5 g in 1 VIAL; Type 0: Not a Combination Product |                     |                      |                    |

# **Marketing Information**

| War Keting Imormation |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final   | part347                                  | 08/20/2016           |                    |
|                       |  |                      |                    |

# Labeler - INNOGENE CO.,LTD (688201056)

# Registrant - INNOGENE CO.,LTD (688201056)

# Establishment

| Establishment    |         |           |                        |
|------------------|---------|-----------|------------------------|
| Name             | Address | ID/FEI    | Business Operations    |
| INNOGENE CO.,LTD |         | 688201056 | manufacture(70540-030) |

Revised: 10/2016 INNOGENE CO.,LTD